

# Is Ethylene Oxide the Cheapest Medical Device Sterilization Method?

A false emerging narrative suggests ethylene oxide (EtO) sterilization is cheaper, easier, and faster than alternatives and thus preferred. Modern Healthcare called it a "relatively cheap process" that easily penetrates products, "making it an attractive choice for device makers." In fact, EtO sterilization is often the most expensive, time-consuming, and inefficient method.

## Medical device makers must choose a method that:

- effectively sterilizes the product while ensuring it is still functional and not damaged
- meets all toxicology requirements post sterilization
- meets FDA's sterilization requirements consistent with device approval
- meets sterile label assertions
- maintains product performance and patient safety

### THE FACTS:

The appropriate sterilization method is determined during the concept and design phase.

The manufacturer determines the right cycle — how much EtO, radiation, or steam, etc. — to apply for how long to achieve sterility.

EtO sterilization requires days (preconditioning, sterilization cycle, heated aeration). The device maker must factor in the time and cost of taking a product out of circulation and manage inventory accordingly.

Many manufacturers are seeking less EtO use on devices to minimize emissions. This can add time to the chamber processing.

**EtO sterilization is the most complicated of the three most common methods.**

**Of critical variables required:**



Radiation, one: dose



Steam, three: time, temperature, pressure



EtO, five: time, temperature, pressure, relative humidity, gas concentration

**These methods are not interchangeable.** Each device is designed with its own sterilization method. Many devices on the market were designed for sterilization only with EtO.

**For devices using alternative methods, costs might vary** with supply chain constraints. For example, gamma radiation relies on cobalt-60.

**An alternative method might take even longer than EtO or work at a smaller scale.** Constraining supplies leads to higher demand and higher prices for consumers.

**Companies also spend money on capital improvements,** such as new EtO capture technology to drive down emissions to almost zero.

**Properly sterilized medical devices are continuously in high demand.** Needs will continue to increase as the population ages and requires more medical care.

**Device makers and sterilizers use the most effective sterilization method for each device** — not the cheapest or fastest — to meet design specifications, FDA requirements, and patient safety without impacting device functionality.

**This is to ensure sterility of the multi-part devices** used to treat patients in hospitals and doctors' offices every day.

## ETO STERILIZATION PROCESS:



### Pre-Conditioning

Medical devices are pre-conditioned using heat and humidity for optimal processing. This step may take place in a dedicated ancillary space or a processing chamber where the product is stored at elevated temperature and humidity for a prescribed amount of time.



### Sterilization

Following pre-conditioning, the medical devices are loaded in the processing chamber, and EtO enters the chamber from an ancillary source. The EtO gas saturates the product, resulting in sterilization.

The in-chamber cycle includes EtO gas evacuation from the sterilization chamber and wash phases prior to aeration.



### Aeration

After sterilization, the product continues to give off small amounts of EtO. During this phase, the medical devices are further degassed within the chamber or in a dedicated ancillary space. The remaining EtO is evacuated from the chamber and destroyed (abated), either by converting it to ethylene glycol or oxidation. The removed gas is destroyed in an environmentally responsible manner.